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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/582,975

06/15/2006

Eric Jervis

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EXAMINER

KETTER, JAMES S

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

09/01/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/582,975 | Applicant(s) JERVIS ET AL. | |
| | Examiner James S. Ketter | Art Unit 1636 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-11,13-15,17-76,80-108,111 and 113-119 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) See Continuation Sheet is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims rejected are 1,6-8,11,13,17-20,22-32,34-38,42,45,46,49-52,54-60,62-66,70,73,74,80-84,86-92,94-98,102,105,106,111 and 113.

Continuation of Disposition of Claims: Claims objected to are 3,5,9,10,14,15,21,33,39-41,43,44,47,48,53,61,67-69,71,72,75-79,85,93,99-101,103,104,107,108 and 114-119.

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Upon further reconsideration of the scope of the claimed invention as well as the cited prior art, it has been determined that a new grounds of rejection is warranted. The newly cited patent to DiMilla et al. (A), applied below, substantially corresponds to the DiMilla et al. PCT publication cited of record (WO 2003/060061 A1). The recitation of the minimum shim thickness of 0.001 inches previously had not been appreciated to the degree that it compares to cellular dimensions. The delay in presenting this rejection is regretted.

Claims 3, 5, 9, 10, 14, 15, 21, 33, 39-41, 43, 44, 47, 48, 53, 61, 67-69, 71, 72, 75-79, 85, 93, 99-101, 103, 104, 107, 108 and 114-119 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 6-8, 11, 13, 17-20, 22-32, 34-38, 42, 45, 46, 49-52, 54-60, 62-66, 70, 73, 74, 80-84, 86-92, 94-98, 102, 105, 106, 111 and 113 are rejected under 35 U.S.C. 102(e) as being anticipated by DiMilla et al. (A, newly cited).

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The instant claims have been discussed of record. Claim 1, for example, is drawn a method of cell culture comprising: confining a cell between first and second barriers, said barriers spaced at a distance to contact said cell and prevent said cell from traveling toward or away from each of said first and second barriers; placing one or more spacers between said first and second barriers to prevent said first and second barriers over-compressing said cell; and providing to said cell a culture substance, wherein said first barrier is urged toward abutment with said second barrier and wherein said confining and said placing comprise at least partially separating said first and second barriers and introducing said cell and said one or more spacers between said first and second barriers.

DiMilla et al. teaches, e.g., as summarized in the Abstract, “The invention features modular chambers for culturing cells in which the volume of a chamber can be adjusted without compromising the seal or sterility of the chamber. The invention is based on the principle that the volume of a chamber formed between two plates sandwiching a compressible gasket and a substantially incompressible stop can be adjusted using a gasket that forms a fluid-tight seal between the plates at a plurality of levels of compression. The invention enables the culture of cells between substantially parallel and rigid plates in which a relatively large volume can be used to seed the cells and the holdup volume reduced for perfusion without opening or otherwise disassembling the system to compromise its liquidtightness and sterility. The new closed, modular and scalable cell-culturing chamber can be thus perfused and used to culture cells (e.g., hepatocytes) with high levels of cell function in organ (e.g., liver) assist systems, for production of cells, for production of cell-derived products, such as proteins or viruses, or for systems to treat biological liquids to remove toxins, such as ammonia, add cell-synthesized products, or

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both.” At column 13, last full paragraph, it is taught that the thickness of the shims separating the plates is greater than 0.001 inches. This equates to 25.4 microns, and even twice this thickness, 50.8 microns, equals the upper range of diameters of hepatocytes (20 to 50 microns), which is the cell type exemplified in DiMilla et al. This also inherently would have produced a monolayer of cells as they grew. The plates in DiMilla et al are compressed toward one another against a compressible gasket, which meets the limitation of “urged toward abutment.” At column 24, last full paragraph, the use of a sensor to measure temperature, pH or flow rate (shear) is taught. At column 10, second full paragraph, the use of clear plastics, e.g., polycarbonate, for the plates is taught. Throughout, particularly in the figures, the use of screws to put tension on the plates and gasket is taught. The invention is taught as a detachable unit which may be regarded as a cartridge.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James S. Ketter whose telephone number is 571-272-0770. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSK
30 August 2010

/James S. Ketter/
Primary Examiner, Art Unit 1636